July 29, 1999

Hon. Nancy-Ann Min DeParle
Health Care Financing Administration
Department of Health and Human Services
Attn: File Code HCFA-1005-P
Room 309-G
200 Independence Avenue, SW
Washington, DC 20201

Re:	The Prospective Payment System for Hospital Outpatient Services—Its Impact on Small and Rural Hospitals; 63 Fed. Reg. 47,552 (September 8, 1998).

Dear Administrator DeParle:

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration was created in 1976 to represent the views and interests of small business in federal policy making activities.[1] The chief counsel participates in rulemakings when he deems it necessary to ensure proper representation of small business interests, and works with federal agencies to ensure that their rulemakings include an analysis of the impact that their decisions will have on small business. The chief counsel also reports to Congress annually on the Regulatory Flexibility Act (RFA)[2] and on federal agency compliance with that statute. The Office of Advocacy welcomes the opportunity to comment on the proposed rule establishing a prospective payment system for hospital outpatient services.

The Balanced Budget Act of 1997 (BBA) called for the implementation of sweeping Medicare reforms to reduce waste and fraud. Among those reforms, is a requirement for the Health Care Financing Administration (HCFA) to develop and implement an outpatient prospective payment system (OPPS). The goal of the OPPS is to control Medicare costs and simplify the current hospital-specific payment system that is largely cost-based. The primary mechanism the OPPS uses to accomplish this goal is a pre-set price structure for groupings of designated outpatient services. The pre-set price is determined by establishing relative payment weights that are based on median hospital costs. Adjustments for high cost (outlier) hospitals and certain other classes of hospitals are permitted under the BBA to ensure equitable payments as long as budget neutrality requirements are met.

[1] Pub. L. No. 94-305 (codified as amended at 15 U.S.C. §§ 634a-g, 637).
[2] Regulatory Flexibility Act, 5 U.S.C. § 601, as amended by the Small Business Regulatory Enforcement Fairness Act, Pub. L. No. 104-121, 110 Stat. 866 (1996). The RFA requires federal agencies to assess and analyze the impact of their regulations on small entities and asks agencies to consider less burdensome alternatives that do not interfere with the agencies' policy or regulatory objectives.

According to HCFA's analysis, the OPPS rule would result in significantly reduced payments for low-volume rural hospitals (75% of low volume hospitals are rural)[3] cancer hospitals, and rehabilitation hospitals. These hospitals would lose 17%, 29.2% and 24.1% respectively. If a substantial number of these hospitals are small, then the payment reductions become especially burdensome because smaller entities have sunk and operating costs which have to be recouped if they are to remain in business.

SBA's definition of a small hospital is one with annual revenues that do not exceed $5 million or one that is a not-for-profit entity. While it is unlikely that the comprehensive cancer centers which are described in the rulemaking are small in terms of annual receipts, it is possible that a number of them are not-for-profit entities. The same is probably true of the rehabilitation hospitals. It is quite possible, on the other hand, that the low-volume rural hospitals might fall into either definition of small.

Because a number of the aforementioned hospitals may be small,[4] particular attention must be paid to the analysis of impacts and reasonable alternatives that might reduce the burden on these small entities. The analysis of small business impacts must take into account whether public policy objectives can be met by alternatives to the regulation and whether a separate payment structure and/or exceptions are appropriate for the above-referenced categories of hospitals. The Office of Advocacy believes that such an analysis will show that low volume rural hospitals should receive outlier adjustments, and that cancer and rehabilitation hospitals should be exempt from OPPS altogether and placed under a separate payment system in order that their financial viability might be maintained and that they may continue to provide their invaluable services to the patient community.

In addition, there are other provisions of the proposed rule that impact all covered facilities—large and small. These provisions, which are outlined below, deal primarily with HCFA's rate-setting methodology.

Types of Hospitals

- **Low Volume/Rural Hospitals**

HCFA expressed concern about the impact of the instant proposal on the 60 percent of low-volume rural hospitals that are sole community hospitals or Medicare-dependent hospitals. HCFA acknowledges that several factors, including lack of economies of scale

[3] 63 Fed. Reg. at 47,599.

[4] Unfortunately, the Office of Advocacy does not have data on the number of small hospitals based on annual receipts. Advocacy's data, which is derived from U.S. Bureau of the Census data, is based on number of employees. Advocacy's 1995 data shows that there are 3,982 general medical and surgical hospitals (SIC 8062) and 471 specialty hospitals which include rehabilitation, childrens' and cancer hospitals (SIC 8069). The **average** of annual receipts for general medical and surgical hospitals with fewer than 100 employees is $2,910,856 (582 facilities), and for specialty hospitals it is $2,506,878 (82 facilities)—far below the $5 million small business threshold. Annual receipts may vary widely between these hospitals based on factors like volume, specialty-specific costs, and regional costs. To view this and other industry data, please access the small business statistics section of Advocacy's website: www.sba.gov/advo/stats/int_data.html

and Medicare dependency, may contribute to the large reduction in payments for low volume rural hospitals under the new payment system.[5] HCFA presents and solicits comments on two alternatives—both of which involve a phase-in of the outpatient PPS—in an attempt to moderate the high payment reductions. The Office of Advocacy believes that a phase-in approach would be appropriate and help alleviate some of the burden associated with the outpatient PPS; however, an upward adjustment of some sort may still be required to help these hospitals survive in the long term under PPS. The economies of scale issue will always be present in these types of low volume and small rural hospitals. As such, a temporary phase-in may do little to assure adequate prospective payment levels in the future.

- **Cancer Hospitals**

Size notwithstanding, there are significant public policy reasons for considering the impact of this proposal on cancer and rehabilitation hospitals. According to industry experts, the majority of cancer patients are now treated in an outpatient setting. Significant reductions in payments might severely upset this mode of specialized and advanced treatment, and force many of these patients back into an (expensive) inpatient setting unnecessarily. It is within the agency's authority to exclude certain services from the OPPS. The discussion and industry analysis below will show that exclusion of services provided by cancer hospitals is an appropriate alternative.

A system of payments that primarily relies on national median hospital costs cannot support the sophisticated and evolving types of treatment provided by cancer hospitals. Moreover, flexibility in providing less expensive or less complex treatment options does not exist to the same degree as in general hospitals. In other words, cancer hospitals do not have the option of balancing expensive complex treatments with other types of patients that require less care (e.g., treatment for a broken bone). A cancer patient fighting against time, and in some cases, against significant survival odds, should be able to receive the fastest and most effective treatment regardless of cost—a fact HCFA has acknowledged and a concept central to the mission of cancer hospitals.

In the past, HCFA has promulgated rules and Congress has enacted laws that reflect an appreciation for the specialized services offered by cancer hospitals. Specifically, in the past, HCFA and Congress have carved out exceptions for cancer hospitals because of a realization that the services provided by cancer hospitals cannot be likened to services provided by general hospitals.[6] Congress has continued to support the idea that cancer hospitals are a "different animal" and require special treatment. This is evidenced by the 1997 BBA provisions for the OPPS that permit the Secretary to "establish a separate conversion factor for [the cancer centers] in a manner that specifically takes into account

[5] 63 Fed. Reg. at 47,599.

[6] In 1983, taking into account the unique mission of cancer hospitals, Congress enacted authorizing legislation that permitted the Secretary of Health and Human Services to provide for exceptions for cancer hospitals under the inpatient prospective payment system. *See* Social Security Act Amendments, Pub. L. No. 98-21, § 601 (1983). In addition, HCFA promulgated implementing regulations for the hospital inpatient prospective payment system that exempted cancer hospitals for reasons identical to those presented herein with regard to the outpatient prospective payment system. *See* 48 Fed. Reg. 39,752 (1983); 49 Fed. Reg. 234 (1984).

the unique costs incurred by such hospitals by virtue of their patient population and service intensity."[7]

The foregoing demonstrates an adequate foundation upon which HCFA can justify different treatment for cancer hospitals—size notwithstanding. It seems that the most prudent course of action that is consistent with the agency's statutory authority and public policy goals is to exempt cancer hospitals at this time based on the unique services they provide and the disproportionately harsh burden that would befall them if no exemption were permitted. Moreover, since the BBA requires HCFA to base relative payment weights on median hospital costs, exemption is the only realistic alternative.

- **Rehabilitation Hospitals**

Although various types of therapy and rehabilitation services are specifically exempt from the outpatient PPS system (i.e., physical and occupational therapy and speech pathology), outpatient rehabilitation hospitals will nevertheless incur drastic payment cuts under the outpatient PPS as proposed. As in the case of cancer hospitals, rehabilitation hospitals provide specialized services that are not taken into account within the outpatient PPS system. Many rehabilitation patients require extra personnel and equipment for even routine visits that are not generally required in normal outpatient settings. For these reasons, the Office of Advocacy recommends exempting rehabilitation hospitals from the outpatient PPS until a methodology can be developed that adequately accounts for the legitimate costs incurred by these hospitals.

Methodology

- **Grouping Services**

Part of the methodology HCFA uses to determine applicable payment rates is to group similar services into Ambulatory Payment Classifications (APCs) so as to determine a single rate for the grouped services. One of the problems with this methodology is that some of the grouped services may actually vary widely in cost. If this were to happen, outpatient facilities would likely receive insufficient payments for expensive or high-end services. Grouping may also discourage the use of more expensive (but more appropriate) treatment. The Medicare Payment Advisory Commission (MedPAC), in its March 1998 report to Congress, expressed similar concerns which HCFA lists in its proposed rule:

- If services in a group are not homogeneous, a single payment rate for all services in the group would not be accurate.
- Hospitals whose case mix includes a greater than average volume of higher-cost procedures in a group with a payment rate based on median costs for all procedures in the group could face losses and would have a financial incentive to provide only the lower-cost procedures within a group and to avoid the higher-cost procedures.
- Grouping services creates considerable administrative burdens and problems related to data consistency, provider education, the need for extensive technical assistance, and modification of claims processing systems.

[7] Balanced Budget Act, Pub. L. No. 105-33, § 4523(a) (1997).

- If costs for services in a group change at different rates, the price for the group may become distorted over time, necessitating periodic rebasing of group weights.
- Using groups to set rates for services under the hospital outpatient PPS moves away from standardizing payment systems across ambulatory settings.[8]

HCFA offers several explanations as to why its approach of using APC groups is appropriate. Some of HCFA's explanations include the following: 1) low procedure volume and questionable cost data for some procedures make individual coding impracticable or unnecessary, 2) as few as 100 codes (out of a total 10,500) account for over a third of all coded services, 3) grouping closely related services, and paying the median cost of the group, discourages upcoding that occurs when individual services that are similar have disparate median costs, etc. These and the other explanations proffered by HCFA are legitimate, but do not seem to address some fundamental problems—that true costs are not accurately reflected and that similar procedures can vary tremendously in cost and this unfairly punishes facilities that utilize a disproportionate amount of high-cost procedures. These cost issues impact the ability of these hospitals—small or large—to compete effectively in the healthcare marketplace.

If HCFA is going to proceed with its proposed methodology, then a serious effort should be undertaken to use the most current data and to ensure that services in fact have similar costs and not just similar procedures.[9] Otherwise, HCFA should consider the option of basing rates on individual services or a fee schedule, and abandon groupings altogether.[10] The later option is consistent with MedPAC's recommendation for the hospital outpatient PPS to be based upon relative weights for each individual service rather than upon groups of similar services to help ensure consistent payments across ambulatory settings.

- **Calculation of Group Weights and Rates**

Section 1833(t)(2)(C) of the Medicare statute requires the Secretary to develop relative payment weights for covered groups of hospital outpatient services. To develop the rates, HCFA to a total of 98 million claims and separated out the 83 million claims that could be matched with a cost report, and further separated those 83 million into single procedure claims (37 million) and multiple procedure claims (46 million). HCFA then decided to use only the single procedure bills, and from those, eliminate the 11 million laboratory procedure claims. Translated, this means that HCFA is using as a basis for calculating group weights 26 million out of 98 million claims. HCFA says it decided on this approach because of their "inability to specifically allocate charges or costs for packaged items and services like anesthesia, recovery room, drugs . . ."[11]

The "slimming down" of the data raises a number of concerns. For instance, a likely result of using a single-claims database will be a misrepresentation of true costs for the

[8] 63 Fed. Reg. at 47,561-2.
[9] This may mean that HCFA needs to increase the number of groupings to account for the cost differentials.
[10] HCFA is not required to group services under the Medicare statute. Section 18333(t)(2)(B) of the Medicare statute provides that the classification system **may** be composed of groups, so that services within each group are comparable clinically and with respect to the use of resources.
[11] 63 Fed. Reg. at 47,572.

care of sicker patients that require complicated and multiple procedures (e.g., cancer patients). In addition, because so many multiple claims have been eliminated from the database, there is no way to ascertain (from the rulemaking itself) whether a sufficient number of single claims exist to calculate an accurate amount for a particular individual service/Current Procedural Terminology (CPT) code. In other words, it may be quite possible that a particular CPT code appeared more frequently in multiple claims than in single claims, and therefore, data which is based on single claims would represent only a small percentage of claims actually paid for that particular code.

Volume Expenditure Target

Under section 1833(t)(2)(F) of the BBA, HCFA is required to develop a method for controlling *unnecessary* increases in the volume of covered outpatient services. HCFA is proposing to accomplish this by establishing an expenditure target for the (calendar) year 2000, and if expenditures in the year 2000 exceed the projected amount, HCFA will reduce the amount for the year 2002 by the amount the target is exceeded. In other words, if the volume of services paid for increases beyond amounts established, then an adjustment is made to account for the discrepancy.

The Office of Advocacy has not been able to determine how HCFA will distinguish between necessary and unnecessary services if HCFA's methods are implemented. It seems that under HCFA's method/interpretation, all services, and not just unnecessary ones, will be impacted. Further, the methodology seems to be more a means to adjust future rates than a methodology to control volume increases. In any event, a target rate that is too low will result in unfair payment reductions. HCFA has a great deal of discretion in determining how to control unnecessary increases in volume, but HCFA should focus more carefully on ways to control only unnecessary increases—as Congress intended the agency to do.

Moreover, Advocacy cannot determine how HCFA will be able to predict a target rate of growth with accuracy because actual spending may vary depending on advances in treatments, technology improvements and other factors that may impact the cost of outpatient services. Target rates can be inherently arbitrary and should be avoided if any other method will achieve the statutory goal of controlling unnecessary volume increases.

Y2K Issues

HCFA has not completed its Y2K-readiness testing and upgrading and has announced that OPPS implementation will be delayed until July 2000—6 months later than scheduled. The Y2K problem has already delayed or complicated implementation of some significant Medicare reform regulations like consolidated billing for skilled nursing facilities. Given the uncertainty about HCFA's level of readiness by the date of implementation, it would be prudent to analyze the adequacy and impact of alternative interim measures until the outpatient PPS can be implemented fully.

First and foremost, HCFA should set a reasonable implementation date to allow for the development and testing of software that Medicare intermediaries will use in implementing OPPS. Premature implementation will only result in confusion and cause hospital outpatient facilities to incur additional reprocessing costs. These reprocessing costs will further reduce the already narrow operating margins for small and rural outpatient facilities.

Second, although HCFA has stated its intention to delay implementation of this regulation, HCFA has not stated its position with regard to interim payment rates for certain outpatient services. Specifically, it is not clear whether HCFA intends to use as an interim rate the current blended rate outlined in section 1833(I)(3)(A) of the Medicare statute or whether HCFA intends to revert to the old method of basing rates on reasonable costs. The uncertainty arises under section 4523(d) of the BBA of 1997 which places a January 1, 1999 sunset restriction on application of the blended rate.

Since blended rates have historically resulted in lower payments in many cases, it is important that HCFA clearly state a legal basis for adopting a blended rate in this case. It is the opinion of the Office of Advocacy, however, that reasonable costs should be used to determine rates. Since the blended rate sunsets, HCFA has the legal authority to revert to the preexisting reasonable cost method. The significance of this interpretation cannot be underestimated because economic savings generated during the interim may help offset some of the revenue losses to be expected under OPPS once it is fully implemented.

Conclusion

Some rules pose a disproportionate burden on small businesses and others pose a burden on the entire industry—including small businesses. This particular proposal may do both. Low-volume and rural hospitals and specialty hospitals (some of which may be small) will bear a disproportionate burden in relation to large hospitals. The methodology and data used to calculate the group rates and the APC groupings impact all hospitals. If beneficiary access to outpatient services is negatively affected because of an inequitable rate-setting process, then beneficiaries may be forced into the more expensive inpatient setting.

The Office of Advocacy does not wish for HCFA to abandon its regulatory objectives and statutory responsibilities in creating an outpatient PPS, but we encourage HCFA to consider the recommendations outlined herein to help alleviate the burden associated with implementation of this important regulation. Please do not hesitate to contact our office if you have any questions at 202-205-6533.

Thank you for your attention to this matter.

Sincerely,

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